

**REMARKS:**

Reconsideration of the rejections set forth in the Final Office Action mailed April 16, 2010 and entry of the present amendment is requested because Applicants respectfully submit that the Amendment places the application in condition for allowance or in better form for consideration on appeal.

In response to the Final Office Action, claim 125 has been canceled without prejudice, claims 104, 126, and 147 have been amended, and new claim 148 has been added. No new matter has been introduced. Accordingly, claims 104-110 and 126-148 are currently pending.

With respect to the Restriction, Applicants have amended claim 104 to include all of the limitations of claim 125, and amended claim 126 to depend from claim 104. Applicants would like to confirm the status of claims 104-110 given these amendments, i.e., that these claims now read upon the elected species.

In the Final Office Action, claim 147 was rejected 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,720,275 ("the Patil reference"), claims 125-126 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Publication No. 2003/ 0149488 ("the Metzger reference") in view of U.S. Patent No. 6,328,753 ("the Zammit reference"), claims 127 and 130-138 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Publication No. 2003/ 0149445 ("the Knudson reference") in view of the Patil reference, and claims 125-126, 128-129, and 139-146 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Knudson reference in view of the Patil reference and further in view of the Zammit reference.

Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the § 102(b) rejection of independent claim 147, the Patil reference discloses a tracheal guide 19 for positioning a medical device 11, such as an intubation tube, in the trachea of a patient. Col. 2, lines 57-60. The tracheal guide 10 includes an elongated member 14 on the end of a tubular proximal portion 36. Col. 2, lines 63-65, FIGS. 1-3. The elongated member 14 includes a generally U-shaped passage 17 and first and second cars 18, 33 disposed laterally about a distal end 15 thereof. Col. 3, lines 16. The elongated member 14 is intended to be positioned about the glottic opening of a trachea 12, i.e., with the cars 18, 33 positioned in the piriform fossa 19, 34, and the tubular portion 36 extending from the trachea out of the patient. Col. 4, lines 18-32, FIGS. 3-5.

In contrast to the Patil reference, claim 147 recites a method for maintaining the patency of an airway of a patient that includes introducing an appliance into an oropharyngeal region of the patient, the appliance comprising a transverse portion between spaced apart end portions, the transverse portion being substantially bow shaped with the appliance at rest, the appliance having a length between the spaced apart end portions and a height transverse to the length, the length greater than the height; and securing the appliance within the oropharyngeal region such that the transverse portion extends at least partially around the oropharyngeal region and the end portions push the tongue forward to hold the airway patent.

First, on page 4, the Final Office Action erroneously identifies the Patil cars 18, 33 as the spaced apart end portions recited in claim 147. These ears cannot properly be considered the end portions, because they do not “push the tongue forward to hold the airway patent. Instead, the Patil reference discloses that the cars 18, 33 are received in the piriform fossa. A person of

ordinary skill would recognize that the ears 18, 33 in this intended position would be too low and incapable of pushing the tongue forward.

Second, the Patil reference fails to disclose, teach, or suggest an appliance that has a length between the spaced apart end portions and a height transverse to the length, *the length greater than the height*, as claimed. If the length dimension is considered the generally “U” shaped perimeter of the Patil elongate member 14, the Patil tracheal guide has a height that is many times greater than that length, since the tracheal guide must be sufficiently long to extend from the trachea out of the patient. Accordingly, for these reasons, claim 147 is neither anticipated by nor otherwise obvious over the Patil reference.

Turning to the § 103(b) rejection of independent claim 125, now claim 104, based upon the combination of the Metzger and Zammit references, the Metzger reference discloses an implant 110, namely a flexible braid of polyester fibers, that is placed in or beneath a mucosal layer to induce a fibrotic tissue response. ¶¶ [0042], [0050]. Although the Final Office Action states that the Metzger “at least one element (112) is substantially bow shaped with the appliance at rest,” no support is identified for this conclusion. Applicants submit that there is no basis for this conclusion in the Metzger reference, and that the Metzger braid is not bow shaped at rest.

Further, the Metzger reference fails to disclose, teach, or suggest inserting the appliance into an oropharyngeal region in a constrained configuration; and *releasing the appliance* within the oropharyngeal region, *thereby allowing the appliance to expand radially* within the oropharyngeal region so that the central body portion extends generally laterally across the posterior wall and the end portions support the lateral walls of the oropharyngeal region, as recited in claim 104. Instead, the Metzger reference discloses placing the implant in or beneath a

mucosal layer, which cannot be accomplished by releasing a flexible braid within the oropharyngeal region.

The Final Office Action erroneously relies on the Zammit reference for teaching the limitations of claim 104 that are missing from the Metzger reference. The Zammit reference fails to teach anything about inserting an appliance including a central body portion between end portions in a constrained configuration and releasing the appliance such that the appliance expands radially within the oropharyngeal region and the end portions support the lateral walls of the oropharyngeal region.

Instead, the Zammit reference merely discloses a collapsible nasal-oropharyngeal tube or device 1. Col. 2, lines 34-35, col. 3, lines 58-60. The device 1 has a tubular mid-section 4 with flared ends 2, 3 that, when expanded, define a lumen 5 intended to provide an unobstructed airway within a nasal passage. Col. 3, line 66 to col. 4, line 6. At least one end of the device can be coiled, folded, or otherwise collapsed as shown in FIGS. 2 and 3 and held in this collapsed state by a retaining fiber, tie, or clasp. Col. 4, lines 7-13. When collapsed, the device 1 can be inserted into a patient's nasal passage via the nostril, and then expanded in the nasal passage so as to push against the oropharynx and nasal passage walls to maintain upper airway patency. Col. 3, lines 52-57, col. 4, lines 31-37.

Thus, the Zammit device 1 is clearly not deployable such that a central body portion extends generally laterally across the posterior wall and end portions support the lateral walls of the oropharyngeal region. Instead, the Zammit device 1 is merely a tube that unfurls. It would not be obvious based on this entirely different structure to modify the Metzger braid, as suggested in the Final Office Action. Further, the Zammit device is not even implanted within the

oropharyngeal region, but is placed in the nasal passage, and, given this entirely different intended method for use, it would not be obvious to combine the Metzger and Zammit references.

Accordingly, for these reasons, claim 104 and its dependent claims are not obvious over the Metzger and Zammit references.

Turning to the § 103(b) rejection of independent claim 127 based on the Knudson and Patil references, on page 6, the Final Office Action concedes that the Knudson reference fails to disclose an appliance including end portions that support the tongue. However, the Final Office Action then erroneously relies on the Patil reference for disclosing such end portions. As explained above, the ears 18, 33 of the Patil reference do not support the tongue, but are received in the piriform fossa above the trachea. Thus, even if the Knudson and Patil references could be properly combined with one another (which Applicants do not concede given the entirely different structure and intended use of the disclosed devices), the combination fails to teach the method of claim 127. Accordingly, claim 127 and its dependent claims are not obvious over the Knudson and Patil references.

Finally, turning to the § 103(b) rejections of independent claims 125 (now 104) and 139 based on the Knudson, Patil, and Zammit references, Applicants submit that there is no reasonable basis for combining these entirely different references. While the Knudson reference discloses expander members for implantation in a pharyngeal airway, the Patil reference discloses a long tubular tracheal guide, and the Zammit reference discloses a tube for insertion in a nasal passageway. The only basis for combining these references is the present application, which constitutes improper hindsight.

In addition, as explained above, the Patil reference fails to teach or suggest the features of the present claims that are wholly absent from the Knudson reference, as explained above. Further, the mere fact that the Zammit tube is introduced in a constrained configuration and allowing the tube to reopen fails to properly suggest an appliance that expands radially within an oropharyngeal region such that end portions support lateral walls of the oropharyngeal region, also as explained above. Accordingly, for these reasons, claim 104, 139 and their dependent claims are not obvious over the cited references.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Applicants hereby petition for any extension of time necessary to make the present response timely. Applicants believe that a one month extension is currently required.

Respectfully submitted,  
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